

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Richard M. Manshardt
Horticulturist
Department of Horticulture
3190 Maile Way
University of Hawaii
Honolulu, HI 96822

Dear Dr. Manshardt:

This letter is in regard to your genetically modified papaya line 55-1, about which you and your collaborator, Dr. Dennis Gonsalves at Cornell University, initiated consultation with the agency in December 1994. The new papaya line has been modified to confer resistance to the ringspot virus by insertion of the coat protein from the ringspot virus.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new papaya line on January 3, 1997. These communications were intended by you to inform FDA of the steps taken to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted it is our understanding that you have concluded that the new papaya line is not materially different in composition, safety, or other relevant parameters from papaya varieties currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0042 and that will be maintained in the Office of Premarket Approval.

Based on the information you have presented to FDA, we have no additional questions concerning the virus resistant transgenic papaya line, 55-1, at this time. However, as you are aware, it is your continued responsibility to ensure that foods you market are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc:HFS-13, HFS-200, HFS-205, HFS-206, HFS-226, HFS-225, HFS-226, HFS-246,
HFS-247, HFV-200, BNF42